Formal verification of medical user interface software in PVS

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Joint work with
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SSFT14 – May 22nd, 2014

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CHI+MED research project

www.chi-med.ac.uk

Long-term aim: to transform the design and use of medical devices so as to help clinicians avoid and recover from human error

Combining a variety of approaches

- Mathematical analysis of device designs
- Contextual studies in hospitals
- Lab-based experiments
- Understanding manufacturer's context
- Public engagement

UCL · Swansea University Prifysgol Abertawe · Queen Mary University of London · City University London · EPSRC Engineering and Physical Sciences Research Council

Formal verification – key achievements within chi+med

1. User interface software

- Verification of safety requirements provided by regulators
- Verification of interaction design principles (e.g., consistency)

2. Socio-technical systems

- Analysis of contextual study data / field observations
- Analysis of incidents reports

3. Tool support for model-based prototyping

- Validation of models, safety requirements, analysis results

4. Case studies based on real medical devices

- We identified previously undetected defects in medical devices in use in hospitals

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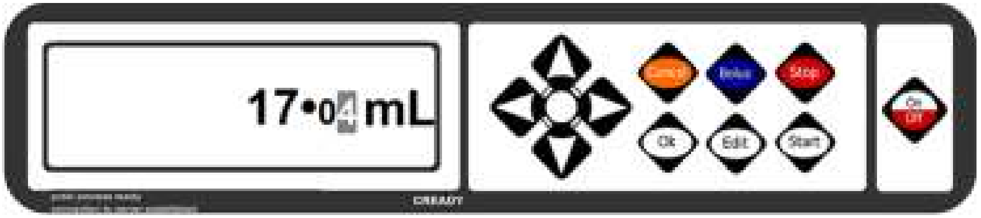
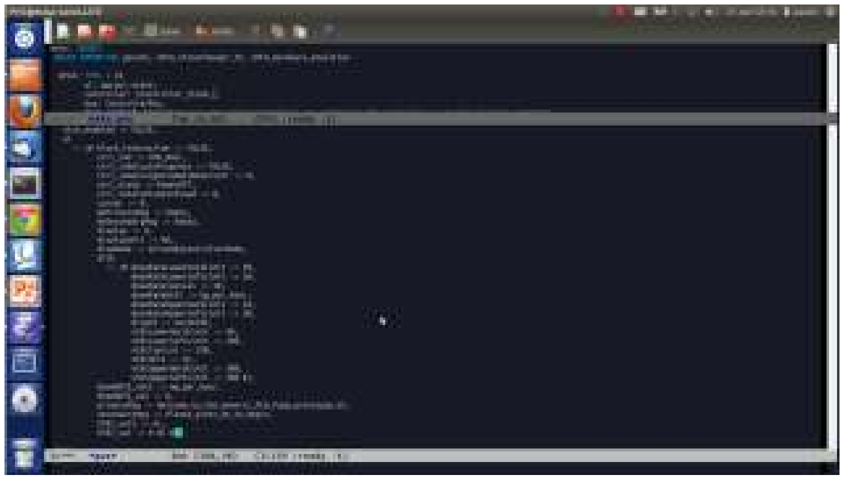
PVSio-web – model-based prototyping in PVS
(www.pvsioweb.org)



Javascript front-end
(defines graphical layout + captures user actions)

User action
(PVS expression)

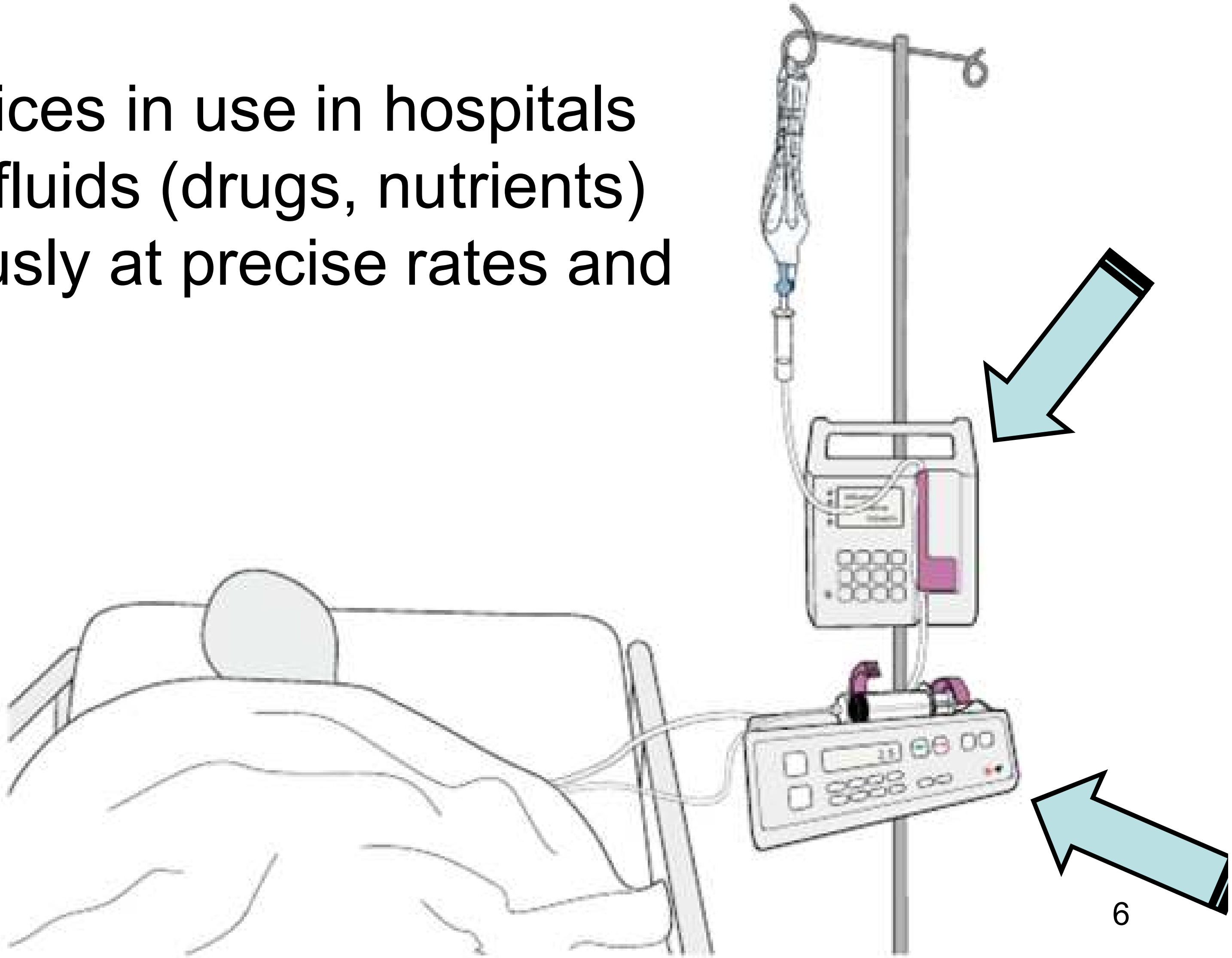
Device response
(evaluated PVS expression)



PVS back-end
(defines the behaviour of the modelled device)

Infusion pumps

Medical devices in use in hospitals to deliver fluids (drugs, nutrients) intravenously at precise rates and volumes.



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Device recalls

Nearly 2,000,000 defective devices recalled in the last decade

- A recall is the removal or correction of a marketed product that regulators consider unsafe (e.g., due to several reported incidents)

Main causes of recalls

- Software defects
- User interface issues

Problems affect all manufacturers and all device models

- Regulators concluded that issues are in the engineering process

Software defects in infusion pumps

Coding bugs

- null pointers, invalid array index, …

Interaction logic bugs

Our approach identifies these bugs

- unexpected device modes
- incorrect feedback
- inconsistent response to user inputs
- …

Examples of interaction logic bugs

Interaction logic
(as explained in the user manual)

- In the Main Menu, open the rate with ◀ and set it with ⁘.

(from the user manual)

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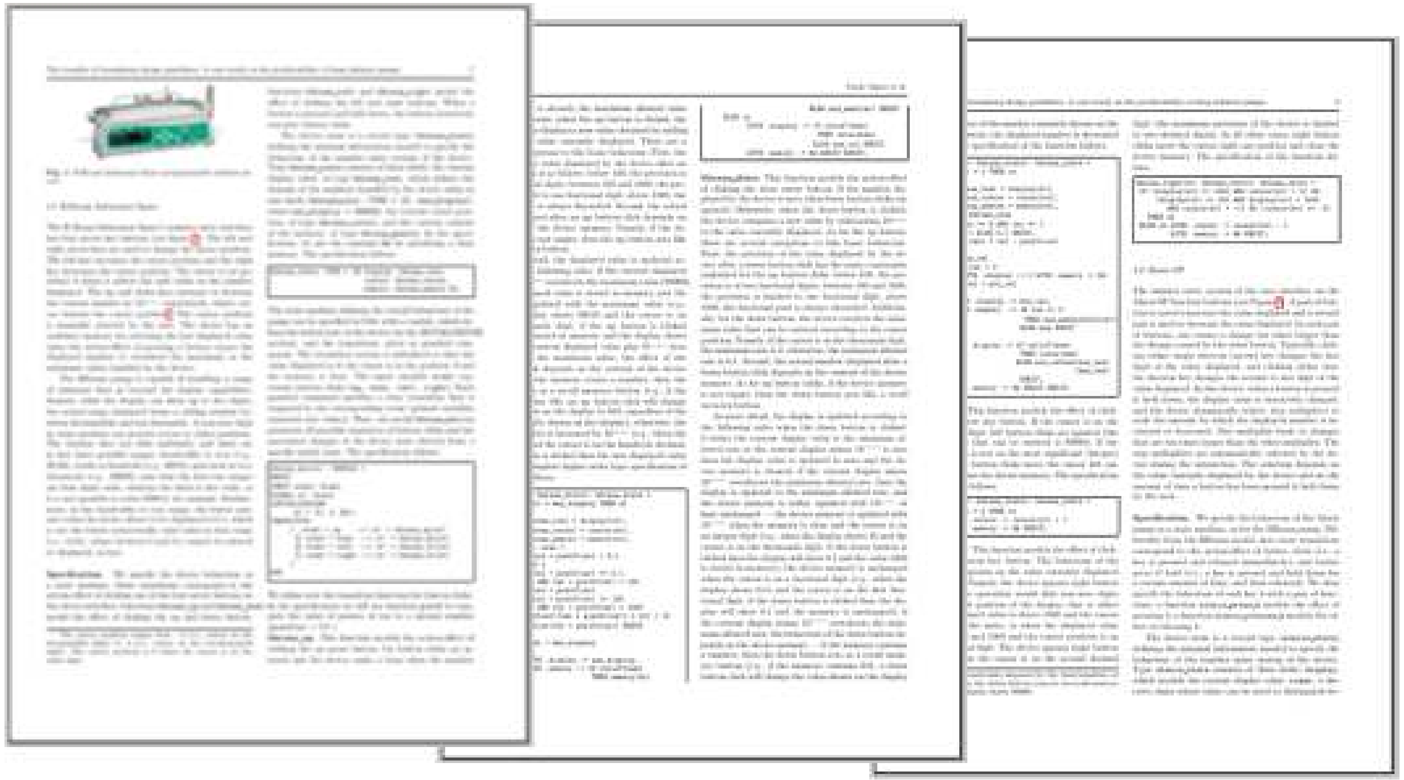
An accurate specification of the interaction logic

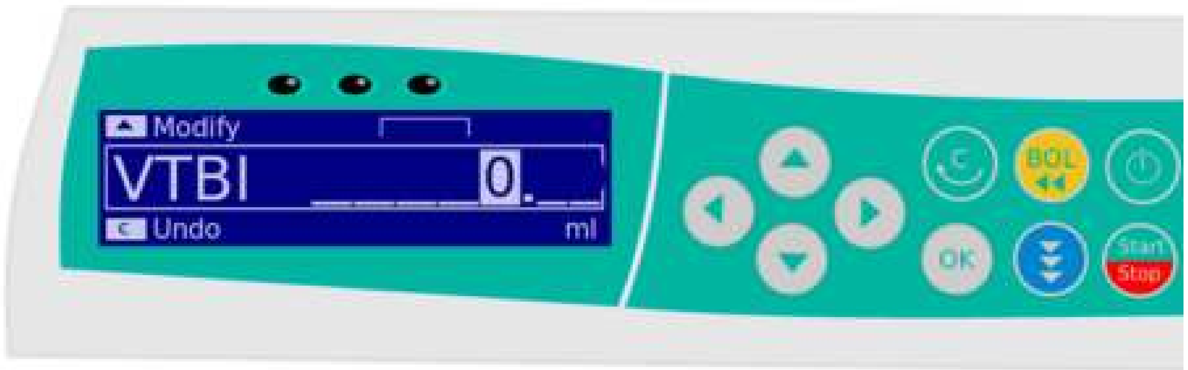
Obtained in our labs by reverse-engineering the real device



Ref: "A case study on the predictability of drug infusion pumps", P. Masci et al,
in Innovations in Systems and Software Engineering, Springer-Verlag London, 2013

Subtle differences in interaction logic

Pump 1



Pump 2

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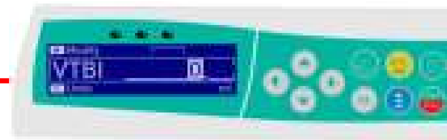
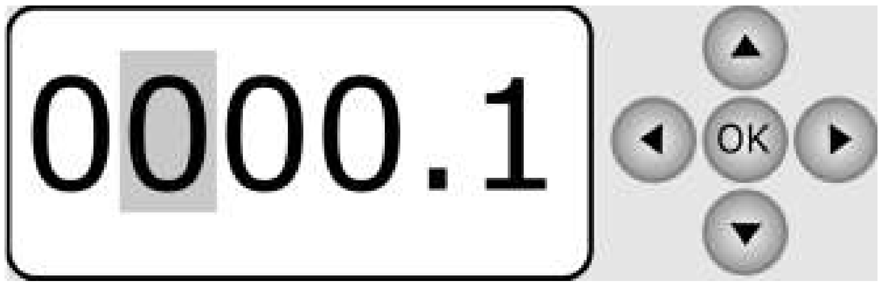
Example task: enter 950mL volume

Key presses: ◀ ▲ (x5) ◀ ▼

Result of key presses on Pump 1





Result of key presses on Pump 2

Ignored key presses

Decimal point erroneously ignored

The key sequence

1	0	0	.	1

is registered as 1001

Devices from different manufacturers have similar problems

The key sequence

1 **0** **0** **.** **1**

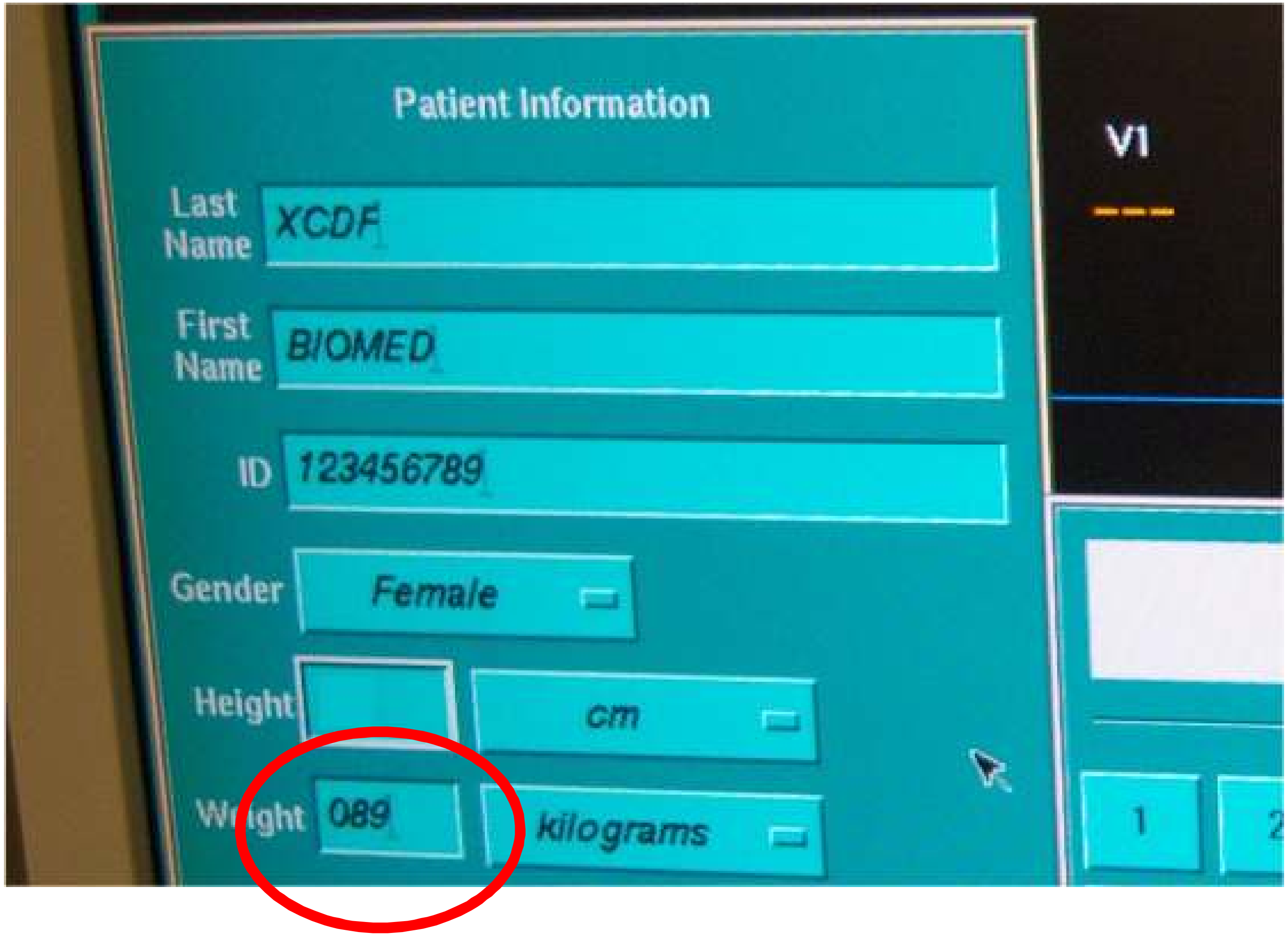
is registered as 1001

(the value is fortunately rejected in this device because the pump configuration limits the rate value to 999 mL per hr)

ill-formed values

Integer values with leading zeros
(they might be easily misread as fractional values)

Patient monitors have similar problems



Discarded values

Discarded values

Entered values are <u>discarded without any warning</u> when input not terminated with "OK"

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Ventilators have the same problem

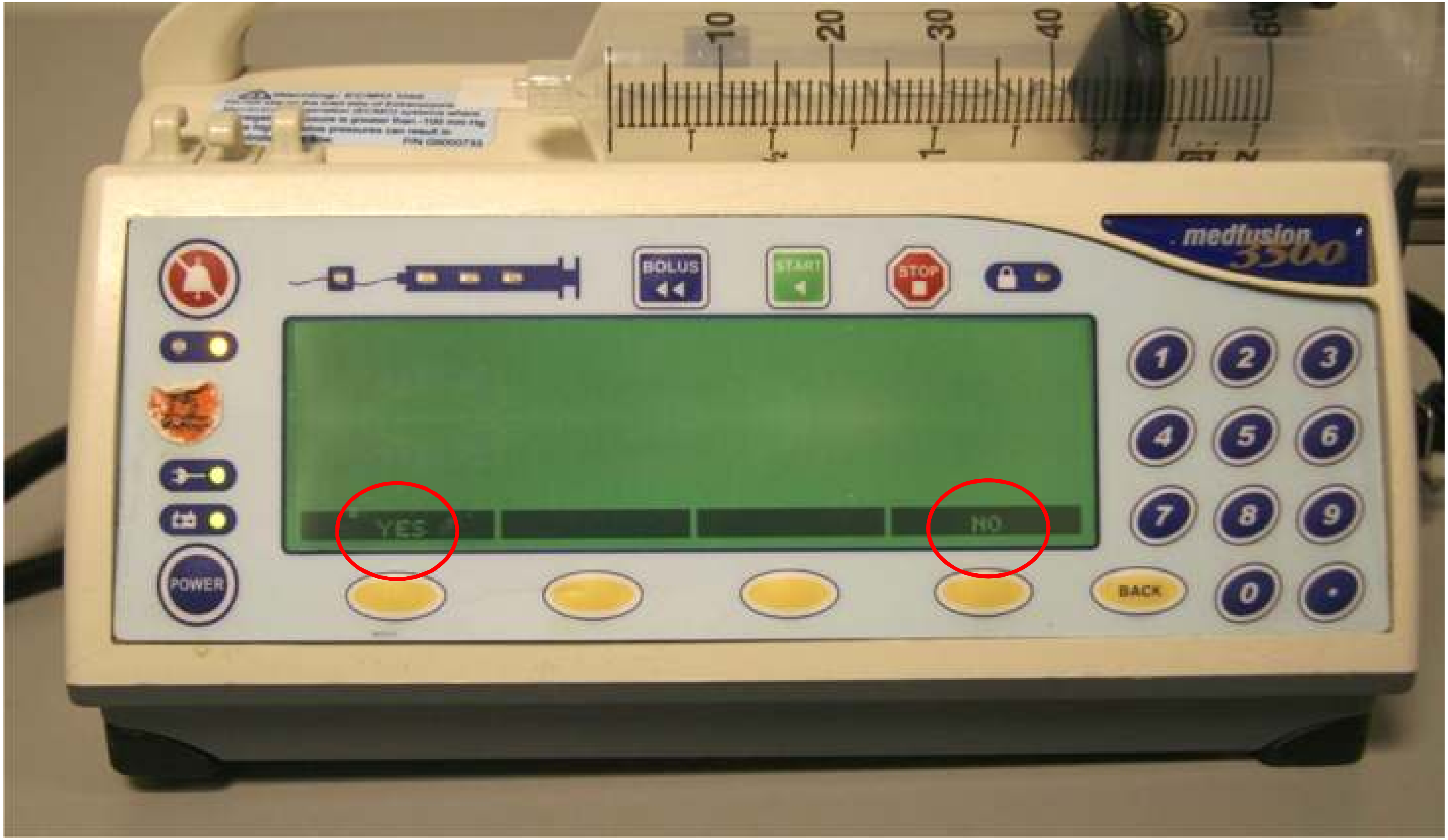
Datex-Ohmeda

Mindray

Draeger Apollo Infinity

Wrong feedback / Non-informative


CareFusion
Alaris PC
Guardrails
A BD Plastipak 10 mL
PRIMARY INFUSION
RATE
0.02 mL/h
VTBI
2 mL
Time Left: < 1 minute
-0.1 is less than MIN RATE
0.1
VOLUME
DURATION
SILENCE
OPTIONS
SYSTEM
ON
Alaris PCA
RATE (mL/h)
CHANNEL
SELECT
PAUSE
CHANNEL
OFF
RESTART
STANDBY


10
20
30
40
medfusion 3500
BOLUS
START
STOP
YES
NO
1
2
3
4
5
6
7
8
9
0
POWER
BACK

Lessons learned

Existing formal tools are effective for the analysis of user interfaces

- We don’t need new formal tools for the analysis of user interfaces, but new front-ends for existing tools!

Model-based prototyping allowed us to engage with key stakeholders

- Clinicians
- Medical device trainers
- Regulators
- Engineers

Key references

“Formal Verification of Medical Device User Interfaces Using PVS.”
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“**Model-based development of the Generic PCA infusion pump**”,
P Masci, A. Ayoub, P. Curzon, I. Lee, O. Sokolsky, H. Thimbleby
in **SAFECOMP2013**, , Intl. Conference on Computer Safety, Reliability and Security, 2013

“**Verification of interactive software for medical devices**”
P Masci, A. Ayoub, P. Curzon, M.D. Harrison, I. Lee, H. Thimbleby
in **EICS2013**, ACM SIGCHI Symposium on Engineering Interactive Systems, 2013

“PVSio-web: a tool for rapid prototyping device user interfaces in PVS”
P. Oladimeji, P. Masci, P. Curzon, H. Thinbleby
in FMIS2013, 5th workshop on Formal Methods for Interactive Systems
http://www.pvsioweb.org

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